What is claimed is:

- A rotational molding system for molding a medical article comprising:
 a multi-axis rotational molding machine; and
 a mold mounted to said molding machine wherein the interior of said mold
 defines a cavity in the desired shape of the medical article to be molded.
- 2. The system according to claim 1 wherein said mold comprises first and second mold pieces matable to form a vacuum-tight seal along mating surfaces between said first and second pieces.
- 3. The system according to claim 1 wherein said mold comprises a sprue opening fluidly connected to said interior of said mold.
- 4. The system according to claim 2 wherein one piece of said mold has a hemispherical cavity shape.
- 5. The system according to claim 1 wherein said interior of said mold is sized to allow for the thickness of a liner to coat an inside surface of said mold.
- 6. A method for molding a medical article comprising the steps of: inserting a molding material into a cavity within a mold; applying a vacuum to said mold;

rotating said molding material in said mold about at least two axes to coat the interior of said mold cavity with said molding material.

- 7. The method of claim 6 further comprising the steps of:
 inserting a liner material into said cavity;
 rotating said liner material in said mold about at least two axes to coat the interior
- 8. The method according to claim 7 wherein said liner material coats the interior of said mold cavity thereby masking any surface irregularities.
- 9. The method according to claim 7 wherein said liner material is a thermoplastic selected from the group consisting of polyethylene, polypropylene, nylon and fluoropolymer.
- 10. The method according to claim 7 wherein said liner material is a thermoset selected from the group consisting of polyester resin, polyurethane and epoxy.
- 11. The method according to claim 6 wherein said molding material is a room temperature acetoxy-cured silicone dispersion in a solvent.
- 12. The method according to claim 6 wherein said molding material is a platinum catalyzed heat-cured silicone dispersion in a solvent.

NY2:#4369152v5 15

of said mold cavity with said liner material.

- 13. The method of claim 7 further comprising the step of separating said liner material from said molding material.
- 14. The method of claim 13 wherein said liner material is separated from said molding material by dissolving said liner material.
- 15. The method of claim 13 wherein said liner material is separated from said molding material by melting said liner material.
- 16. The method of claim 13 wherein said liner material is separated from said molding material by burning said liner material.
- 17. The method of claim 13 wherein said liner material is separated from said molding material by peeling said liner material from said molding material.
- 18. The method of claim 6 further comprising the step of removing the medical article from the mold through an opening in the mold left by a sprue.
- 19. The method of claim 6 further comprising the step of inserting a filler material into said mold cavity.
- 20. The method of claim 19 further comprising the step of curing said filler material.

- 21. A system for rotationally molding a medical article comprising:

 means for rotating a mold about at least two axes;

 means for molding a material within said mold into the form of the medical article;

 means for inserting a molding material into said mold; and

 means for supplying vacuum to said mold.
- 22. The system of claim 21 further comprising means for inserting a liner material into said mold.
- 23. A multi-axis rotationally molded medical article comprising:a shell defining an interior cavity;

said shell being formed of at least one layer of a silicone selected from the group consisting of room temperature acetoxy-cured silicone and platinum catalyzed heat-cured silicone, and tin catalyzed silicone.

- 24. The medical article of claim 23 wherein said shell is textured.
- 25. The medical article of claim 23 wherein said shell is seamless.
- 26. The medical article of claim 23 wherein said shell is patchless.

- 27. The medical article of claim 23 where said shell has a thickness of from about 0.005 inches to about 0.06 inches.
- 28. The medical article of claim 23 further comprising a filler material contained within said interior cavity.
- 29. The medical article of claim 28 wherein said filler material is a silicone gel.
- 30. The medical article of claim 28 wherein said filler material is a saline solution.
- 31. The medical article of claim 28 wherein said filler material is a foam.
- 32. The medical article of claim 23 further comprising a removable liner.
- 33. The medical article of claim 31 wherein said liner is a thermoplastic selected from the group consisting of polyethylene, polypropylene, nylon and fluoropolymer.
- 34. The medical article of claim 31 wherein said liner is a thermoset selected from the group consisting of polyester resin, polyurethane and epoxy.
- 35. The medical article of claim 23 wherein said article is a medical implant.
- 36. The medical article of claim 35 wherein said article is a breast implant.

- 37. The medical article of claim 23 wherein said article is an elastomeric balloon.
- 38. The medical article of claim 23 wherein said article is a catheter balloon.